

REMARKS

Amendments in the specification

Amendment of “sertralin” to “sertraline” in paragraph [0054] is requested to correct a typographical error.

Amendments in the claims

Claims 9–82 are now pending in the application. Claims 9, 12–15, 18, 21, 23 and 27–28 are amended from those of record in Amendment A of the present application. Claims 29–82 are new according to this amendment. Each of these claims finds support in the application as filed, as indicated below.

Opportunity has been taken when preparing the present amendment to correct obvious typographical errors and to add further clarity to the claims by rewording or repunctuating where appropriate.

Claim 9 is amended to specify a “therapeutic” combination. The specification as a whole provides support for a “therapeutic” combination. It is clear from the specification as filed that the utility of the combination is for treating a disease (*i.e.*, therapeutic).

Claims 9, 27 and 28 are amended to enhance clarity by defining the one or more additional active ingredients in language that more explicitly embraces not only a single additional active ingredient but also combinations of two or more additional active ingredients. Support is found in the specification as filed, at least at paragraph [0052], where it is stated that “other active ingredients . . . may also be present”.

Claim 12 is amended to delete without prejudice the phrase “or an organic depression not associated with Parkinson’s disease”. The embodiment deleted from this claim remains the subject of Claim 14.

Claims 13–15, 21 and 23 are amended as to dependency and to more clearly specify the antecedent class of depression recited therein.

Claim 18 is amended to specify “about” 50 mg per day as the upper end of the recited dose range. Support is found in the specification as filed, at least at paragraph [0047], which indicates “about 50 mg/day.”

Claim 27 is amended to delete without prejudice selected additional active ingredients.

Combinations comprising these additional active ingredients are the subject of new Claims 73–80.

New Claims 29 and 31 recite rotigotine or a metabolite, prodrug or salt thereof administered in monotherapy. Support is found in the specification as filed, at least at paragraphs [0027], [0028] and [0052].

New Claim 30 recites alleviation of symptoms of Parkinson's disease and treatment of depression. Support is found in the specification as filed, at least at paragraphs [0027] and [0028].

New Claims 32–44 recite types of depression arranged in a hierarchy as set forth in the specification as filed, at least at paragraphs [0018]–[0020], [0026], [0029] and [0037].

New Claims 45–47 recite dosages of rotigotine or a metabolite, prodrug or salt thereof of 0.1 to about 50 mg per day; 0.2 to 40 mg per day; and 0.4 to 20 mg per day respectively. Support is found in the specification as filed, at least at paragraph [0047].

New Claims 48–59 recite plasma rotigotine concentrations of 0.05 to 20 ng/ml; 0.1 to 10 ng/ml; 0.2 to 5 ng/ml; and 0.1 to 0.5 ng/ml. Support is found in the specification as filed, at least at paragraph [0037].

New Claims 60–69 recite administering additional active ingredients. Support is found in the specification as filed, at least at paragraphs [0054], [0055] and [0057]–[0062].

New Claim 70 recites that the rotigotine or metabolite, prodrug or salt thereof and the one or more additional active ingredients are present in separate dosage forms adapted for administration by the same or different routes at the same or different times. Support is found in the specification as filed, at least at paragraphs [0057] and [0058].

New Claim 71 recites that the rotigotine or a metabolite, prodrug or salt thereof and the one or more additional active ingredients are present in a single dosage form. Support is found in the specification as filed, at least at paragraph [0057].

New Claims 72–80 recite combinations of Claim 9, wherein the one or more additional ingredients are specified. Support is found in the specification as filed, at least at paragraphs [0054] and [0059]–[0062].

New Claim 81 recites that the rotigotine or metabolite, prodrug or salt thereof and the

one or more additional active ingredients are present in separate dosage forms adapted for administration by the same or different routes at the same or different times. Support is found in the specification as filed, at least at paragraphs [0057] and [0058].

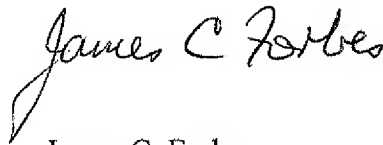
New Claim 82 recites that the rotigotine or metabolite, prodrug or salt thereof and the one or more additional active ingredients are present in a single dosage form. Support is found in the specification as filed, at least at paragraph [0057].

No new matter is added, and no changes in inventorship are believed to result from the present amendment.

Examination of the present application is requested following entry of this amendment. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

A handwritten signature in black ink that reads "James C. Forbes". The signature is written in a cursive, flowing style with a large initial "J".

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